WATSON MARLOW Fluid Technology Solutions

Your OEM partner for medical devices and in vitro diagnostics

OEM peristaltic pumps and tubing

Market experience

When it comes to designing your healthcare equipment, you need a partner you can trust to provide reliable pump and fluid transfer path solutions.

As a provider of peristaltic pumps and fluid path technologies, Watson-Marlow Fluid Technology Solutions (WMFTS) enables leading companies worldwide to overcome the challenges of bringing medical and diagnostic solutions to market.

For over 60 years, manufacturers of medical devices and diagnostic instrumentation (or clinical diagnostics) have integrated, catalogue and tailored solutions from WMFTS into their equipment.

Peristaltic pumps have long been synonymous with medical devices due to their hygienic design and gentle fluid handling of blood or other sensitive fluids. The fluid is contained within the tubing that can become part of the low-cost consumables that can be replaced with each procedure. This provides peace of mind to patients and process security to device developers and manufacturers.

Watson-Marlow pumps serve a wide range of applications in medical devices and diagnostics. Customers use our products in their designs for:

- Cardiovascular devices
- Orthopaedic surgery
- Nephrology and urology devices
- In vitro diagnostics (IVD)
- Surgical equipment
- Endoscopy
- Dental

Characteristics of peristaltic pumps:

- Inherently hygienic by design, with no valves or seals
- No contamination as the fluid is sealed within a tube
- Pump tubing is easily incorporated into medical single-use tube sets or cassettes
- Multiple tube sizes can be used in the same pump to change the capacity of the pump
- Ease of operation/maintenance
- Accurate and repeatable flow rates
- Reversible flow direction
- Self-priming and dry running
- Careful handling of precious fluids (low sheer, low pulse)






Pumps you can rely on

In **cardiac ablation**, Watson-Marlow pumps are used within medical devices that cool the catheter tip during tissue ablation at precise flow/pressures. The temperature at the ablation zone needs to be highly controlled to ensure effective treatment whether using radiofrequency, microwave, or laser heat sources. This means pumps need to deliver saline at precise flow rates, overcoming high back pressures due to the narrow lumen in the catheters used. Our RXMD panel mount pump incorporates an adjustable pressure relief so as not to exceed the maximum specifications of the catheter. *See case study on page 14.*

During **minimally invasive surgery**, fluid management equipment in surgical environments must be simple and intuitive for medical staff to use. A consistent smooth saline delivery and quiet operation aids procedural repeatability with minimised noise distraction. In minimally invasive treatments for benign prostatic hyperplasia (BPH), also called an enlarged prostate, Watson-Marlow pumps are used within medical devices which can aspirate (to draw fluids by suction) and collect tissue and fluids from the treatment site.

In **endoscopy**, our pumps are used as a component within medical devices for irrigation and visualisation during endoscopic procedures, as well as endoscope cleaning in reprocessing systems. The 313D pumphead is a component within a medical device for a single-use colonoscope, to continually rinse the integral camera lens during examination to ensure the surgeon has good visibility throughout the procedure.

An ageing population and the increasing need for cancer and heart disease diagnosis is driving demand for **in vitro diagnostics** (IVD) test equipment. Watson-Marlow pumps are a critical component of the customer device and play a key part in liquid handling in diagnostics, such as sample aspiration, reagent addition, probe and cuvette washing, and removing liquid waste.

In **orthopaedic surgery**, Watson-Marlow pumps are part of a device that irrigates the surgical site and remove spent fluid and particulates due to their ability to pump solids and air. One example is the use of an ultrasonic bone-cutting device to perform osteotomies (bone re-shaping and alignment). The speed the device cuts through bone enables short operation times, an efficient procedure and preservation of healthy bone compared to drills. The device uses a pump to irrigate the surgical site with saline so surgeons can see what they are doing, and also removes debris from the wound.

During **home dialysis**, Watson-Marlow pumps within the device are part of the process to mix, recirculate and filter dialysate that is created by powders mixed with tap water. This eliminates the handling and delivery of up to 240 litres of solution needed for each procedure. This innovation in dialysis has transformed the lives of patients due to the benefits of more frequent treatment at home. Pumps are needed to operate reliably for extended periods and against back pressure, to ensure consistent mixing of batches of dialysate. The pump must not generate a lot of noise, so the patient can sleep during the procedure.

Our solutions for medical devices

114DV and 313D

114DV

Whether a medical device is designed to diagnose, analyse, sterilise, or treat, the **114DV** and **313D** fliptop pumps have been designed into hundreds of devices for irrigating, cooling, flushing or dispensing applications. The iconic flip-top design for fast and error-free tube loading makes these pumps a popular choice in many medical device applications.

The **114DV** is for low flows up to 510 ml/min with accurate performance, and flexibility of the pumping range with seven tube sizes in different materials rated for medical use. The **114DV** OEM range offers intuitive rapid tube loading and delivers accurate, repeatable, low-pulse flow rates in a compact size.

313D

This model features a spring-loaded track and comes in standard and high-pressure versions capable of achieving up to 5 Bar. The **114DV** is available in a range of colours to match a customer's design or branding. The six roller **116DV** is designed for lower pulsation and higher accuracy.

313D is for flow rates up to 2,000 ml/min and is extendable for up to six channels of flow*. The three-roller **313D** pumphead offers maximum flows and great flexibility of the pumping range with nine tubing sizes in many different materials. The four-roller **314D** is designed for lower pulsation and higher accuracy. Engineered custom multi-roller options are available on request. The **313D** is available in a range of colours to match a customer's design or branding.

400RXMD series panel mount pumps

400RXMD

The **400RXMD** panel-mount pump meets demands of medical devices serving the surgical ablation market. It is a component of an application that accurately controls the delivery of cooling fluid to the target tissue to achieve a more effective treatment and prevent scarring. **400RXMD** is for flow rates up to 500 ml/min and minimises tube loading errors. The ability to factory-set the pump for pressures up to 8 bar (116 psi) means the pressure/flow profile can be fine-tuned to the requirements of each application and prevents over-pressurising. WMFTS tests every pump to each customer's specific test protocol.

See the full range of solutions available at wmfts.com/panel-mount-pumps/

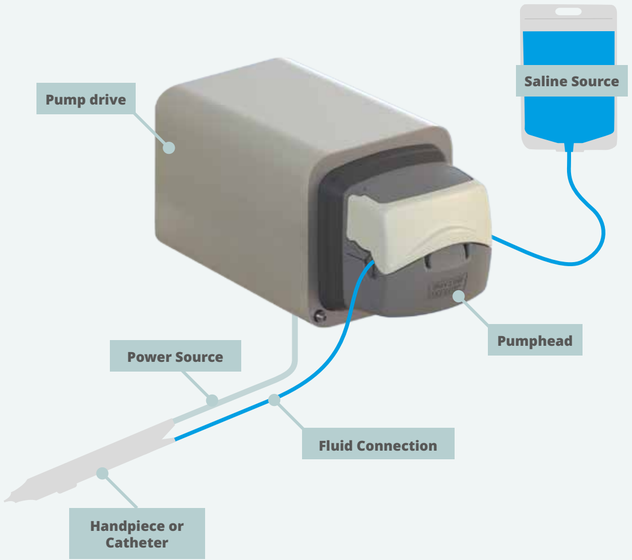
*Depending upon the application

Watson-Marlow pumps in medical devices

Medical device application pump options

Pumphead	114DV	313D	400RXMD
Typical Applications of customer device			
Irrigation	•	•	•
Catheter Cooling			•
Aspiration	•	•	•
Capabilities			
Max Continuous Flow	340 ml/min	2000 ml/min	500 ml/min
Max Pressure	5 bar (72 psi)	2 bar (29 psi)	6 bar (87 psi) *Custom versions to 8 bar (116 psi)*

Our products as a component in a medical device



114DV

400A

400M and 400N

300MC

Our solutions for diagnostic instruments

114DV, 400M, 400N, 300MC

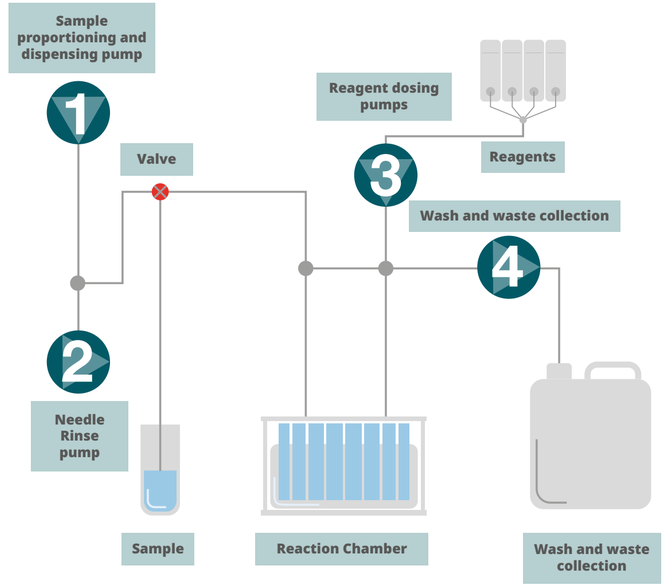
The 114DV and 313D fliptop pumps have been designed into hundreds of devices for sample proportioning, rinsing, reagent dosing, and waste removal. The iconic flip-top design for fast and error-free tube loading/ maintenance makes these pumps a popular choice in many diagnostic device applications.

The **114DV** flip-top pumphead is ideal for sample handling, reagent dosing, and rinsing applications. The **114DV** is for low flows up to 510 ml/min. For precise control of low flow rates, the **400A** is the smallest pump in our range for micro flows from 30 µl/min to 30 ml/min. There is one version for continuous tubing and another for tube elements. The **400M** and **400N** range of multi-channel pumpheads use tube elements with either Luer or barbed connectors for easy connection and replacement, particularly when mounted inside instruments. Tubing is fully enclosed in the housing. The **400N** is capable of running eight flow channels simultaneously. **400M** and **400N** pumps have a flow rate up to 200 ml/min.

300MC micro-cassette pumpheads are designed for multi-channel low-flow, low pulsation applications. For simple tube changes without disturbing other channels, cassettes are pre-loaded with tubing, which is available in 20 sizes and three different materials.

See the full range of solutions available at wmfts.com/panel-mount-pumps/

Watson-Marlow pumps in the in vitro diagnostics process



Solutions for applications shown in the diagram

Pumphead	1	2	3	4	Max Continuous Flow *	Max No. of Channels *
400A	•	•	•		30 ml/min	1
300MC			•	•	53 ml/min	10 *2 ganged heads*
400N			•	•	150 ml/min	8 *4 ganged heads*
400M	•	•	•	•	260 ml/min	4 *4 ganged heads*
114DV	•	•	•	•	340 ml/min	1
400R	•	•	•	•	1060 ml/ min	4
313D	•	•		•	2,000 ml/ min	6*

* Depending upon the application

Image courtesy of Eppendorf

Complete panel-mount solutions

Watson-Marlow panel-mount pumps are available with a range of motors, including stepper and brushless DC motors with integrated control; easy PLC and microcontroller integration (featuring both network and analogue versions); bare stepper motors, or brushed DC motors for OEM integration with optional encoders.

Watson-Marlow **DriveSure™** integrates motor, mounting and in-house control technology to deliver great performance as a single-source solution. DriveSure is fully tested and certified, ensuring reliability in a range of applications.

As a complete panel-mount solution, **DriveSure** helps OEMs to reduce time-to-market, providing competitive gain. Furthermore, the inherent risks of buying various system components from different manufacturers are eliminated, with the assurance of a single, comprehensive two-year warranty.

DRIVESURE

Tubing

Tubing is at the heart of every peristaltic pump and is essential for optimal performance. To work properly it must have the right specifications, such as dimensional tolerances, shore hardness, and elastic modulus.

WMFTS is the only peristaltic pump manufacturer to make its own tubing. We engineer our tubes to work with our pumps as a complete and proven solution.

Manufactured in a our ISO 14644-1 class 7 cleanrooms and rigorously tested, our tubing is available in over 40 sizes that carry a USP Class VI and FDA ratings, with the latest in non-contact continuous measurement systems that ensures quality of every batch. Our validated tubing delivers accurate, repeatable and long-term pumping performance.

Pumpsil® platinum-cured silicone tubing is USP Class VI and FDA compliant. This exceptionally pure tubing offers an ultra-smooth bore that helps minimise protein binding and ensures high purity in the finished product. Pumpsil is widely used for single-use medical irrigation/flushing, filtration and waste transfer applications. It is the best choice when accurate metering is required.

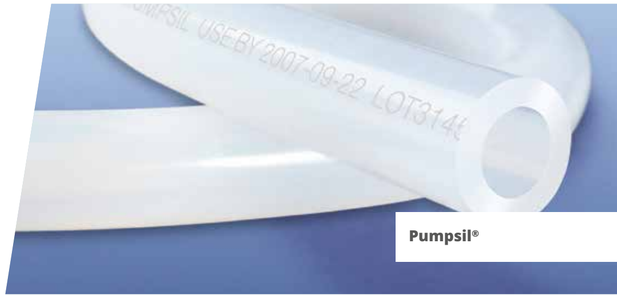
Bioprene® peristaltic pump tubing is USP Class VI and FDA compliant and suitable for in-vitro diagnostic applications such as metering, transfer and filtration. Bioprene's long peristaltic life reduces the maintenance requirements and ensures process security.

PureWeld® XL is USP Class VI and FDA compliant, and is designed for secure, cost-effective peristaltic pumping and transfer duties. It delivers exceptional life and accurate flow rates compared to other TPE tubing and is compatible with other weldable tubing.

You can count on WMFTS for fully documented biocompatibility and comprehensive validation packs for all our tubing products.

Find out more about our tubing at: wmfts.com/wmtubing

Bioprene®



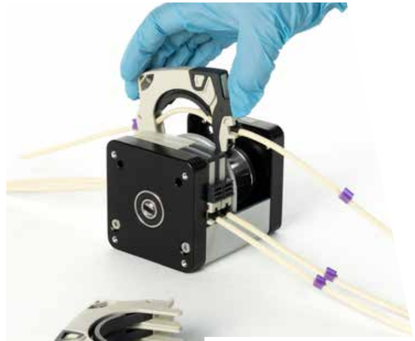
Pumpsil®

PureWeld® XL

Encoders and motors

Multiple colour options

New configurations of core technology



Cassette solutions

Solutions through the whole product lifecycle

Whether you are a start-up or a leading listed global medical device manufacturing company, WMFTS has a proven capability of aligning its products and services to ease your design and supply challenges.

Our dedicated OEM team includes sales engineers who can visit you anywhere in the world, with OEM engineering teams at each factory ready to support you. Together they help to optimise the functionality and performance of the fluid pumping systems in your medical device.

WMFTS understands that off-the-shelf products are merely a starting point. We customise our standard products for a complete and tested solution from a single supplier which meets the appearance, functionality and performance needs of your medical device design requirements.

Our customisation capabilities include:

- Custom colours
- Encoders
- Motors
- Cabling
- Integrated cover-open sensor
- Logo-free versions
- Completely new designs based on our core technology
- Cassette Solutions

Support for the whole product lifecycle

Concept | **Preclinical development** | **Clinical development** | **Pre-production** | **Commercialisation** | **Mature production**

WMFTS engineers assist from the design process through to production, helping to get to market as quickly and efficiently as possible.

- After selection and consultation with our product expert sales and applications engineers, we provide rapid delivery of samples, from our range of standard configurations
- We deliver the sample and help get it operating in the customer's prototype or test lab
- We then offer further consultation with our factory engineers to customise and optimise the product for the customer's application
- Once in production, our robust ISO9001: 2015 quality systems ensure consistent quality over time, traceability and a thorough change management system to support the needs of validated industries

HAT500® RF ablation system from OSYPKA

Case study:

400RXMD plays a key role in cardiac ablation system

Medical device manufacturers livetec Ingenieurbüro GmbH and OSYPKA have integrated a 400RXMD peristaltic pump from WMFTS into their cardiac ablation system.

Chosen for its reliability and ease of operation, the OEM pump is specifically designed for surgical ablation systems with simple integration (which reduces time and cost associated with extended installation), low noise levels and precise control. The 400RXMD is available with DriveSure which integrates motor, mounting and supports Industrial Ethernet as well as analogue protocols.

Germany-based livetec's medical technology products are sold either directly under its own brand name livetec® or as a private label under the brands of many established manufacturers. Sometimes it is both, as in the case of RF liveGEN Generator for high-frequency catheter ablation, which is available on the market under both its own brand and as HAT500® RF ablation system from OSYPKA, a pioneer of RF (radiofrequency)

400RXMD on OSYPKA and livetec's irrigation pumps

RF liveGEN Generator from livetec

ablation and manufacturer of reliable, high quality medical devices. The ablation system developed by livtetec and OSYPKA consists of the RF generator, a remote control unit and an irrigation pump (the 400RXMD) for flushing and cooling the catheter during cooled ablation procedures. Together, they form a comprehensive system for almost all ablation applications on the human heart.

RF liveCOOL (1-60 mL/min), from livetec, is a low-noise irrigation pump for use with high-frequency ablation generators to perform cooled radiofrequency ablation therapies on the human heart. RF liveCOOL works with the RF liveGEN generator to control the flush flow depending on the RF energy output.

The peristaltic pump for irrigation, which is usually mounted directly on the infusion stand, transports the saline solution from an infusion bag or bottle to the tip of the catheter. As it is absolutely crucial that no air enters the bloodstream during treatment, the medical device offers permanent detection of air bubbles from 2 µl with automatic stop, as well as vital permanent monitoring and display of pressure and flow rate. The 400RXMD used as the irrigation pump sucks the saline solution from the infusion bag and conveys it into the catheter via a thin tube.

Michael Schirmeier, Managing Director of livetec, said: "Ablation treatments usually take several hours and the pump must provide saline solution continuously during this time, so absolute reliability of all components is of course essential.

"The pump must be easy to operate. Above all, however, it has to overcome the high back pressure caused by very narrow catheter channels with a very small diameter (lumen) in the micrometer range. Despite the high back pressure, it must be possible to control the flow rate absolutely precisely at any time, so that the exact volume flow required for the respective treatment step is achieved. The peristaltic pump is one of the central components in the system and must provide absolute reliability over several years and many treatments."

The 400RXMD offers flow rates of up to 500 mL/min and a pressure of up to 8 bar, so it can handle the high back pressure present in ablation applications.

Michael Schirmeier added: "During operation, the pump has to deliver three different flows. The most challenging is certainly the flush flow at the start of the treatment, which ensures that there is no more air in the tubes. Depending on the catheter, the pump must perform up to 80 mL/min while the catheter is connected to the tubing-set. This results in high back pressures of up to 5 bar through the narrow catheter channels or irrigation holes. But the pump is easily able to overcome the back pressure without exceeding the pressure limits that could damage the catheter.

"None of the other pumps we tested could deliver similar delivery rates and they were not as good in terms of mechanical compatibility as the Watson-Marlow 400RXMD. The pump and drive can be installed easily in the overall system of the irrigation pump."

WATSON MARLOW Fluid Technology Solutions

MEDICAL DEVICES AND DIAGNOSTICS

WATSON MARLOW Pumps

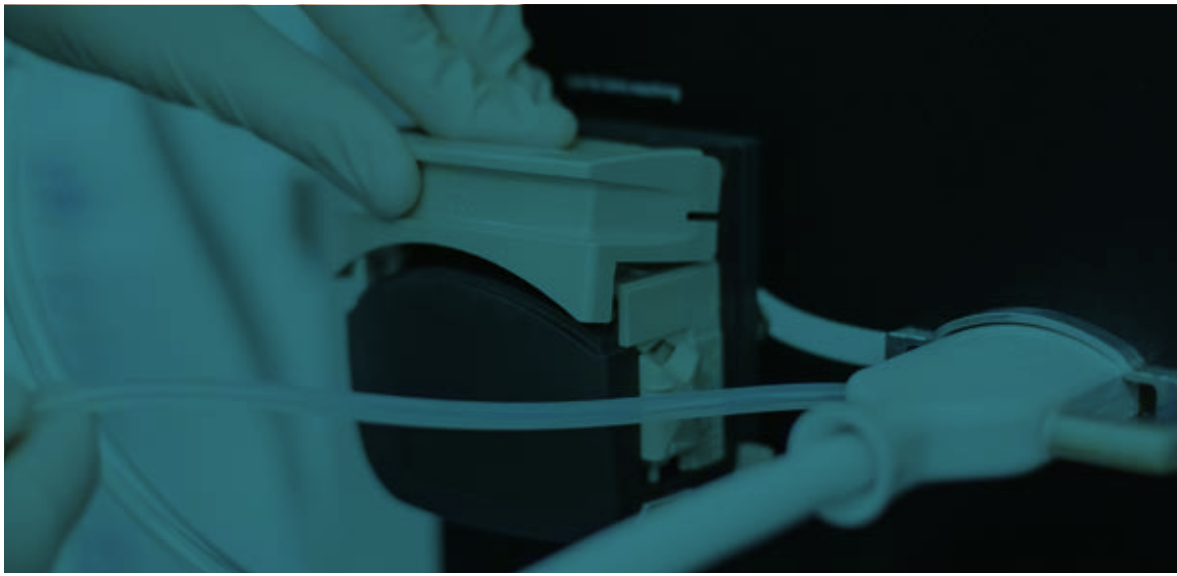
WATSON MARLOW Tubing

Watson-Marlow Fluid Technology Solutions

Watson-Marlow Fluid Technology Solutions supports its customers locally through an extensive global network of direct sales operations and distributors

wmfts.com/global

wmfts.com/medical-devices
wmfts.com/medicaloem



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